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OSMM&N File No. 4625-038-55X DIV By: JPL:SEC:mms

Serial No.: New Application

In the Matter of the Application of: Prem S. PAUL et al.

For: VACCINES RAISING AN IMMUNOLOGICAL RESPONSE AGAINST VIRUSES CAUSING PORCINE RESPIRATORY AND REPRODUCTIVE DISEASES, METHODS OF PROTECTING A PIG AGAINST A DISEASE CAUSED BY A RESPIRATORY AND REPRODUCTIVE VIRUS, A METHOD OF PRODUCING A VACCINE WHICH RAISES AN IMMUNOLOGICAL RESPONSE AGAINST A VIRUS CAUSING A PORCINE RESPIRATORY AND REPRODUCTIVE DISEASE, AND DNA OBTAINED FROM A VIRUS CAUSING A PORCINE RESPIRATORY AND REPRODUCTIVE DISEASE

The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon:

- ☒ (COPY) 137 pp. Specification & 30 Claims/Drawings 37 Sheets
- ☒ (COPY) Combined Declaration, Power of Attorney and Petition (3 pp., executed)
- ☐ Letter with List of Inventors Names and Addresses
- ☒ Rule 60 Application ☐ Rule 62 Application
- ☐ Notice of Priority ☐ Priority Doc. ( )
- ☒ Check for \$ 770.00 ☒ Dep. Acct. Order Form
- ☐ Assignment \_\_\_\_\_ Pp./Form PTO-1595
- ☐ Letter to Official Draftsman
- ☐ Letter Requesting Approval of Drawing Changes
- ☐ Drawings \_\_\_\_\_ Sheets
- ☐ Letter
- ☒ Preliminary Amendment
- ☐ Information Disclosure Statement ☐ Form
- ☐ Cited References ( )
- ☐ \_\_\_\_\_ Search Report
- ☐ Statement of Relevancy
- ☐ IDS/Related/List of Related Cases
- ☐ Restriction Response ☐ Election Response
- ☐ Rule 132 Declaration
- ☐ Petition
- ☐ Notice of Appeal
- ☒ White Advance Serial Number Card



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

Sir: This is a request for filing a

☐ Continuation

Application under 37 C.F.R. §1.60.

☒ Divisional

of copending prior application Serial No. 08/131,625, filed on October 5, 1993

of Prem S. PAUL; Patrick G. HALBUR; Xiang-Jin MENG; Young S. LYOO; and Melissa Anne LUM (Inventor(s))

for VACCINES RAISING AN IMMUNOLOGICAL RESPONSE AGAINST VIRUSES CAUSING PORCINE RESPIRATORY AND REPRODUCTIVE DISEASES, METHODS OF PROTECTING A PIG AGAINST A DISEASE CAUSED BY A RESPIRATORY AND REPRODUCTIVE VIRUS, A METHOD OF PRODUCING A VACCINE WHICH RAISES AN IMMUNOLOGICAL RESPONSE AGAINST A VIRUS CAUSING A PORCINE RESPIRATORY AND REPRODUCTIVE DISEASE, AND DNA OBTAINED FROM A VIRUS CAUSING A PORCINE RESPIRATORY AND REPRODUCTIVE DISEASE

1. "Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or Declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application Serial No. 08/131,625, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon."
2. A verified statement to establish Small Entity status under 37 CFR 1.9 and 1.27
  - ☐ is enclosed
  - ☐ was filed in prior application Serial No. and such status is still proper and desired (37 CFR 1.28(a)).
3. The filing fee is calculated below:

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL	11-20=	0	X \$22=	\$0.00
	INDEPENDENT	1-3=	0	X \$80=	\$0.00
	MULTIPLE DEPENDENT CLAIMS			+ \$260=	\$0.00
				BASIC FEE =	\$770.00
				TOTAL OF ABOVE CALCULATIONS =	\$770.00
	REDUCTION BY 50% FOR FILING BY SMALL ENTITY				N/A
				TOTAL	\$770.00

4. ☒ The Commissioner is hereby authorized to charge any fees which may be required for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Account No. 15-0030. A duplicate copy of this sheet is enclosed.
5. ☒ A check in the amount of \$770.00 is enclosed.
6. ☒ Cancel Claims (SEE ENCLOSED PRELIMINARY AMENDMENT)
7. ☒ Amend the specification by inserting before the first line the sentence:  
     --This is a    ☐ Continuation,    ☒ Division, of application Serial No. 08/131,625 filed on October 5, 1993, now pending; which is a continuation-in-part of application Serial No. 07/969,071 filed on October 30, 1992, now abandoned--.
8. ☒ Thirty Seven (37) Sheets of Drawings are enclosed.
9. ☐ Priority of the following foreign application(s) is claimed under 35 U.S.C. 119:

Country

Application No.

Month/Day/Year

The certified copy(s) of the corresponding Convention Application(s):

- ☐ were filed in prior application Serial No. , filed .
  - ☐ are being submitted herewith.
  - ☐ will be submitted prior to payment of the Final Fee.
10. ☒ The prior application is assigned to: Solvay Animal Health, Inc. and Iowa State University Research Foundation, Reel No.: 6905, Frame Nos.: 541-545.
  11. ☒ The Power of Attorney in the prior application is to one or more of the following: Norman F. Oblon, Reg. No. 24,618; Marvin J. Spivak, Reg. No. 24,913; C. Irvin McClelland, Reg. No. 21,124, Gregory J. Maier, Reg. No. 25,599; Arthur I. Neustadt, Reg. No. 24,854; Richard D. Kelly, Reg. No. 27,757; James D. Hamilton, Reg. No. 28,421; Eckhard H. Kuesters, Reg. No. 28,870; Robert T. Pous, Reg. No. 29,099; Charles L. Gholz, Reg. No. 26,395; Vincent J. Sunderdick, Reg. No. 29,004; William E. Beaumont, Reg. No. 30,996; Steven B. Kelber, Reg. No. 30,073; Robert F. Gnuse, Reg. No. 27,295; Jean-Paul Lavalleye, Reg. No. 31,451; Timothy R. Schwartz, Reg. No. 32,171; Stephen G. Baxter, Reg. No. 32,884; Martin M. Zoltick, Reg. No. 35,745; Robert W. Hahl, Reg. No. 33,893; Richard L. Treanor, Reg. No. 36,379; Steven P. Weihrouch, Reg. No. 32,829; John T. Goolkasian, Reg. No. 26,142; Marc R. Labgold, Reg. No. 34,651; William J. Healey, Reg. No. 36,160; Richard L. Chinn, Reg. No. 34,305; Steven E. Lipman, Reg. No. 30,011; Carl E. Schlier, Reg. No. 34,426; James J. Kulbaski, Reg. No. 34,648; Catherine B. Richardson, Reg. No. 39,007; Richard A. Neifeld, Reg. No. 35,299; J. Derek Mason, Reg. No. 35,270; and Jacques M. Dulin, Reg. No. 24,067, all of OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C., Fourth Floor, 1755 Jefferson Davis Highway, Arlington, Virginia 22202.
  - ☒ The power appears in the original papers of the prior application. (Copy enclosed).
  - ☐ Since power does not appear in the original papers, a copy of the power in the prior application is enclosed.
  - ☐ Recognize as Associate Attorney and address all future communication to:
  12. ☒ Preliminary Amendment is enclosed.
  13. ☒ Also enclosed: White Advance Serial Number Card

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: :

Prem PAUL, et al. :

SERIAL NUMBER: New Application :

FILED: Herewith :

FOR: VACCINES RAISING AN IMMUNOLOGICAL RESPONSE AGAINST VIRUSES CAUSING PORCINE RESPIRATORY AND REPRODUCTIVE DISEASES, METHODS OF PROTECTING A PIG AGAINST A DISEASE CAUSED BY A RESPIRATORY AND REPRODUCTIVE VIRUS, A METHOD OF PRODUCING A VACCINE WHICH RAISES AN IMMUNOLOGICAL RESPONSE AGAINST A VIRUS CAUSING A PORCINE RESPIRATORY AND REPRODUCTIVE DISEASE, AND DNA OBTAINED FROM A VIRUS CAUSING A PORCINE RESPIRATORY AND REPRODUCTIVE DISEASE

PRELIMINARY AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

Prior to examination on the merits, please amend the above-identified application as follows:

IN THE CLAIMS

Please cancel Claims 1-30.

Please add the following new claims:

31. A naturally occurring isolated virus selected from the group consisting of ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-1327 (VR 2431) and ISU-1894.

32. The isolated virus of Claim 31, wherein said virus has less than 90% polynucleotide identity to Lelystad virus in any one of open reading frames 5 (SEQ ID NO:12), 6 (SEQ ID NO:15) or 7 (SEQ ID NO:18).

33. A composition comprising the isolated virus of Claim 31 and a physiologically acceptable carrier.

34. A vaccine which protects a pig against porcine reproductive and respiratory syndrome (PRRS), comprising a <sup>211</sup> inactivated or attenuated virus and a physiologically acceptable carrier, wherein prior to inactivation or attenuation, said virus is the virus of Claim 31. *prepared in serum pool and maintained*

35. The vaccine of Claim 34, wherein lung lesions in said pig are reduced by a statistically significant amount, wherein said amount is significant at a p value less than 0.01, relative to lung lesions in uninoculated five-week-old colostrum-deprived, caesarean-derived pigs.

36. The vaccine of Claim 34 comprising an effective amount of said inactivated or attenuated virus which lowers the average clinical respiratory score of a group of pigs inoculated with said vaccine, then subsequently challenged with live PRRS virus, relative to a group of identically challenged pigs not inoculated with the vaccine.

37. The vaccine of Claim 34 further comprising an adjuvant.

38. A method of protecting a pig from a porcine reproductive and respiratory disease, comprising administering an effective amount of the vaccine of Claim 34 to a pig in need of protection against said disease.

39. The method of Claim 38, wherein said vaccine is administered orally or parenterally.

40. The method of Claim 38, wherein said vaccine is administered intramuscularly, intradermally, intravenously, intraperitoneally, subcutaneously or intranasally.

41. The method of Claim 38, wherein said vaccine is administered to a sow in need of protection against said disease.

**REMARKS**

Claims 31-41 are currently pending in the application.  
Examination on the merits is now respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
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